DETAILED ACTION

Applicant's amendment in the reply filed on 5/4/09 is acknowledged, with the cancellation of Claims 2-5, and 16, and newly added claims 24 and 25. Claims 1, 6-15, and 17-25 are pending. **Claims 1, 6-15, and 17-25 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 112, 1st New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-15, and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

This is a new rejection necessitated by the Applicant's amendment filed on 5/4/09.

Claims 1, 15, and 24 recite "100 mg anthocyanodises, 100 mg procyanidins, or 100 mg of the phloroglucinols" in the claims. However, the specification fails to provide any support regarding the description of "100 mg". Therefore, it is not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, Applicant had possession of the "100 mg anthocyanodises, 100 mg procyanidins, or 100 mg of the phloroglucinols" in the composition of the invention. Thus, the subject matter of "100 mg" is a new matter that needs to be cancelled.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, first paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7, 8, 15, 18, and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yaloveny Agric Ind (SU 1373398A), as evidenced by Nieuwenhuizen et al (US 2003/0064937)*, and Cooper et al (US 6,379,720)*.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 1/2/09, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Yaloveny Agric Ind teaches a composition comprising grapes and extract of hops (see Abstract, the rejection is based on the Abstract))

As evidenced by Nieuwenhuizen et al (US 2003/0064937), grape contains procyanidins [0023, 0077].

As evidenced by Cooper et al, hops (the same as *Humulus lupulus*, col 1, lines 50-55) extract contains alpha acids (phloroglucinols), represented by humulone and its congeners

(cohumulone, admululone) and beta acids, represented by lupulone and its congeners (colupulone, adlupulone) (col 1, lines 50-58).

Yaloveny Agric Ind does not teach the claimed amount of the components in the composition.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the invention of Yaloveny Agric Ind since the composition of Yaloveny Agric Ind yielded beneficial results in food industry, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, and 6-15, and 17-23 remain rejected, and claims 24 and 25 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Walker et al (US 5,474,774), Imaoka et al (JP 06179609 A), Barney et al (US 5,370,863), Van den Berghe (US

6,284,289), and Zou (CN 1421240), as evidenced by Gorenbein et al (US 5,955,102)*, Nieuwenhuizen et al (US 2003/0064937)*, Cooper et al (US 6,379,720)*, Ghosal (US 6,224,906)*, and Appendino et al (Oligomeric acylphloroglucinols from myrtle (*Myrtle communis*), Journal of Natural Products, 65 (3): 334-8, 2002)*.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 1/2/09, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Walker et al teach a composition for inhibiting the adhesion of *E. coli* bacteria to surfaces in a mammalian oral cavity (thus administering to a patient) (claim 1). Walker et al also teach that the invention comprises an extract made from plant material of plant species of the genus *Vaccinium*, and which is significantly enriched for an activity that interferes with adhesion of bacterial cells to surfaces (col 1, lines 42-46). Walker et al further teach that *V. myrtilis* (bilberry), etc are useful species (col 1, lines 63-67).

As evidenced by Gorenbein et al, bilberry extract (the same as *Vaccinium myrtillus*, col 3, lines 10-15) contains anthocyanoside.

Imaoka et al teach a composition with high antibacterial activity on oral bacteria (thus administering to a patient) comprising grape extract (see Abstract, the rejection is based on the Abstract).

As evidenced by Nieuwenhuizen et al (US 2003/0064937), grape contains procyanidins [0023, 0077].

Barney et al teach a composition for inhibiting undesirable gram positive microorganisms in the oral cavity bacteria proliferation (thus administering to a patient) comprising hops acids (col 1, lines 5-10).

As evidenced by Cooper et al, hops (the same as *Humulus lupulus*, col 1, lines 50-55) extract contains alpha acids (phloroglucinols), represented by humulone and its congeners (cohumulone, admululone) and beta acids, represented by lupulone and its congeners (colupulone, adlupulone) (col 1, lines 50-58).

Van den Berghe teaches a composition for treating cold sores (infection in oral cavity) (thus administering to a patient) comprising *Myrtus communis* and *Hypericum perforatum* (col 4, lines 14-22).

As evidenced by Ghosal, St. John's Wort extract (the same as *Hypericum perforatum*, col 1, lines 10-15) contains phloroglucinols and procyanidins (cols 2&3, Table 1).

As evidenced by Appendino et al, *Myrtus communis* contains phloroglucinols (see Abstract).

Zou teaches a composition for treating sore and swelling throat, acute pharyngitis, and acute laryngitis (oral cavity infection) (thus administering to a patient) comprising mint oil (see Abstract, the rejection is based on the Abstract).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for treating oral cavity infection. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for treating oral cavity infection.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating oral cavity infection. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re* Sussman, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables because

they have the ability for treating oral cavity infection, which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Walker et al, Imaoka et al, Barney et al, Van den Berghe, and Zou since all of them teach compositions for oral cavity infection individually in the art. Since all the compositions yielded beneficial results in for oral cavity infection, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claim 11 is a product-by-process claim. It is deemed that the product disclosed by Van den Berghe is not materially differently from the claimed *Myrtus communis* extract, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se*.

Applicant argues that "Distinctions of the present invention over the applied art references have been made of record in the application. These distinctions pointed out the inability of the applied art to assert prima facie unpatentability of the present invention and the unexpected results rebutting any unpatentability set forth in the signed Declaration filed May 7, 2008. For brevity these distinctions are not repeated here. Further, independent claims 1 and 15 of the present invention have been instantly amended to better conform with the unexpected results set forth in the signed Declaration filed May 7, 2008. It is also believed that the newly presented claims are also covered by the unexpected results set forth in the Declaration, including combinations of A+B+C and B+C such as is set forth in Tables 1 and 2, reproduced below" (page 12, 3rd to 5th paragraph).

This is not found persuasive. The Declaration filed on 5/7/2008 does not commiserate with the scope of the current claims. First of all, according to the Declaration, it is required that components A+B+C or B+C are all present in the composition so as to accomplish unexpected result. However, current claim 1 only requires at least one of 100 mg anthocyanodises, 100 mg procyanidins, or 100 mg of the phloroglucinols. The Declaration does not show that at least one of the A, B or C component at 100 mg has unexpected result. Secondly, the Examiner offered allowance through Examiner's amendment based on 200 mg of anthocyanodises, 200 mg

procyanidins, and 200 mg of the phloroglucinols all present in the composition, Applicant declined the offer. Thirdly, the currently amended claims recite "100 mg anthocyanodises, 100 mg procyanidins, or 100 mg of the phloroglucinols" in the claims, and "100 mg" is a new matter that is not supported by the specification, thus the amended claims are not allowable.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655